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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
COPPINS, JANET L	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/784,631	FERNANDEZ-POL, JOSE A	
	Examiner	Art Unit	
	Janet L. Coppins	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-53 and 65-114* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *13-53 and 65-114* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 13-53 and 65-111 pending in the application.

Response to Amendment

1. Receipt is acknowledged of Applicants' Response and Amendment D, submitted 10/24/2003, which has been previously reviewed by the Examiner, as well as Applicants' Amendment of February 16, 2004, in which a full set of pending claims is submitted. Accordingly, claims 81 and 109 have been amended, and new claims 112-114 have been added. Therefore, claims 13-53 and 65-114 are now pending.

Election/Restrictions

2. This application discloses and claims a plurality of patentably distinct inventions. Applicant has cancelled all claims directed to the originally presented invention, and through several amendments in the prosecution history, has added over 100 newly presented claims that are independent or distinct from the invention as originally claimed. Furthermore, this application contains the following inventions or groups of inventions in the claims, which are independent and distinct from each other, including patentably distinct preparations and uses within each invention. For these reasons provided below, restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 13-19, drawn to a metal ion chelating agent, classified in various subclasses of class 546. This group is directed to the invention as represented by original presentation.

II. Claim 20, drawn to a metal chelating agent according to claim 18, additionally containing at least one isotonic vehicle, saline vehicle, and nebulizing agent, classified in various subclasses of class 514.

III. Claims 21-24 & 38-39, (in part), and 25-27, drawn to methods of using compositions containing a metal ion chelating agent, wherein the composition is an intranasal solution, classified in various subclasses of class 514.

IV. Claims 21-24 & 38-39, (in part), and 28-29, drawn to methods of using compositions containing a metal ion chelating agent, wherein the composition is a systemic medicament, classified in various subclasses of class 514.

V. Claims 21-24 & 38-39, (in part), and 30-32, drawn to methods of using compositions containing a metal ion chelating agent, wherein the composition additionally contains a nebulizing agent, classified in various subclasses of class 239.

VI. Claims 21-24 & 38-39, (in part), 33-35, and 40, drawn to methods of using compositions containing a metal ion chelating agent, wherein the composition is a topical lotion, classified in various subclasses of class 514.

VII. Claims 21-24 & 38-39, (in part), and 36-37, drawn to methods of using compositions containing a metal ion chelating agent, wherein the composition is an ophthalmic preparation, classified in various subclasses of class 514.

VIII. Claims 21-24, 33, & 38-40, (in part), and 41-42 drawn to methods of using compositions containing a metal ion chelating agent, wherein the composition

contains a topical lotion and is a formulation for treating inflammation associated with acne, classified in various subclasses of class 514.

IX. Claims 43-47, drawn to a systemic preparation containing a metal ion chelating agent according to the formula of claim 43, classified in various subclasses of class 546.

X. Claims 48-53, drawn to an intranasal solution containing a metal ion chelating agent, classified in various subclasses of class 514.

XI. Claims 65-69, drawn to an ophthalmic preparation containing a metal ion chelating agent, classified in various subclasses of class 514.

XII. Claims 70-74, drawn to a lavage containing at least one metal ion chelating agent, classified in various subclasses of class 514.

XIII. Claims 75-78 drawn to a preservative containing at least one metal ion chelating agent, classified in various subclasses of class 252.

XIV. Claims 79-83 drawn to a method of using a metal chelating agent for preserving an item, classified in various subclasses of classes 252 and 514.

XV. Claims 84-86 drawn to a method of using a metal chelating agent for treating inflammation associated with acne, classified in various subclasses of class 514.

XVI. Claims 87-95 drawn to a method of using a metal chelating agent for removing a metal ion from a metalloprotein, classified in various subclasses of class 420. A further election of a single disclosed species within claim 92 will be required if this Group is elected.

XVII. Claims 96-99, drawn a method of using a metal chelating agent for inhibiting the activity of a heat shock protein, classified in various subclasses of class 530.

XVIII. Claims 100-103, drawn to a method of using a metal chelating agent for inhibiting cell growth, classified in various subclasses of class 514. A further election of a single disclosed species within claims 101 and 103 will be required if this Group is elected.

XIX. Claims 104-106, drawn an immunogenic composition containing a metal chelating agent covalently bound to a metalloprotein, classified in various subclasses of class 420.

XX. Claim 107, drawn to a method of preparing an immunogenic composition that contains a metal chelating agent, classified in various subclasses of class 514.

XXI. Claim 108, drawn to a method of using a metal chelating agent for modulating an immune response in an individual, classified in various subclasses of class 514.

XXII. Claims 109 and 112, drawn to a composition containing a metal chelating agent and an interferon.

XXIII. Claims 110, 111, 113, and 114, drawn to a method of using a metal chelating agent to control replication of a virus, classified in various subclasses of class 514.

3. The compounds of Groups I-XXIII differ materially in composition, method, and element so much so as to be patentably distinct. The inventions include different preparations, different functions, and different effects, and have achieved a separate status in the art and

require searches that are not co-extensive. In addition, a reference that anticipates one group may not even render obvious the other. Accordingly, restriction is required under 35 U.S.C. 121.

All inventions falling outside the class(es) and subclass(es) of the elected Group above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. (The provisions of 35 U.S.C. 121 apply with regard to double patenting covering divisional applications).

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Should Applicant refuse to elect, based on the traversal that the inventions are not patentably distinct, then all claims will be rejected under the same 35 U.S.C. 102(b) reference.

Rationale Establishing Patentable Distinctiveness Within Each Group

5. Each Group listed above is directed to or involves the use of compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over either of the other inventions (Groups), i.e. they are patentable over each other. Chemical structures that are similar are presumed to function similarly, whereas chemical that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with

the holdings of **Applications of Papesch**, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and **In re Lalu**, 223 USPQ 1257 (Fed. Cir, 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

The above Groups represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:

6. Inventions (I-III, IX-XIII, & XIX) and (IV-VIII, XIV-XVIII, & XXI-XXIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the products can be practiced with other materially different products, i.e. there are many other pharmaceutical agents known in the art, for example, for treating hepatitis C, sun burn, angiogenesis, colon cancer, etc. Therefore separate search conditions are involved, which would impose a burden if unrestricted.

8. Inventions I-III, IX-XIII, & XIX are patentably distinct from each other because the preparations differ one from the other as defined by the different requirements recited in each claim, and as a result, are mutually exclusive of each other. The many different preparations claimed are independent and distinct formulations, and can not be searched co-extensively. For example, a topical lotion (i.e. for sunburn) cannot be said to have the same application as an intranasal solution that contains a nebulizing agent (i.e. as an inhalant), or the same application as systemic preparation (i.e. as an intravenous injectable solution), nor can they be said to have

the same classification. Furthermore, the function and concentration of metal chelating agent present and the absence or presence of additives in each of the above formulations differ enough such that each composition claim excludes the other claims directed to different preparations/formulations. Therefore, absent factual evidence to the contrary, each is a different composition, and a serious burden is imposed on the Examiner to perform a complete search of the defined areas.

9. The Inventions of Groups IV-VIII, XIV-XVIII, & XXI-XXIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together an they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). The current state of the art in treating diseases is normally compound- and disease-specific, thus are highly individualized. The instant methods are distinct and independent from each other because all diseases are not obvious variants of each other, i.e. they do not share common metabolic pathways, etc. The instant claims recite methods of treating such a diversity of diseases of different itiologies, for which a community of shared properties can not be found. For example, treating the symptoms of acne by administering an anti-inflammatory results from a specific itiology that is completely different from controlling the replication of a virus by administering an anti-viral. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

10. Inventions XX and (IV-VIII, XIV-XVIII, & XXI-XXIII) are distinct because they are directed to different statutory classes of inventions and the practice of one would not result in

practice of the other invention, i.e. treating sun burn is not a process that prepares *per se* the metal chelating agents.

11. Inventions (I-III, IX-XIII, & XIX) and XX are related as product and process of making thereof. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process as claimed can be used to make another materially different product or (2) that the product as claimed can be made by another materially different process (MPEP 806.05(f)). In the instant case, the product as claimed can be made by another materially different process since there are many other immunogenic compositions known in the art, that are not prepared by utilizing the instant claimed process.

12. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II, and is not required for Groups III-XXIII, etc., restriction for examination purposes as indicated is proper.

Advisory of a Rejoinder

13. The following is a recitation of MPEP 821.04, Rejoinder:

> Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02(c) and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.
> Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product by way of amendment pursuant to 37 CFR 1.121. In view of the rejoinder procedure, and in order to expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of prosecution. Process claims which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance. Amendments submitted after final rejection are governed by 37 CFR 1.116. Process claims which do not depend from or otherwise include the limitations of the patentable product will be withdrawn from consideration, via an election by original presentation (see MPEP § 821.03). Amendments submitted after allowance are governed by 37 CFR 1.312. Process claims which depend from or otherwise include all

the limitations of an allowed product claim and which meet the requirements of 35 U.S.C. 101, 102, 103, and 112 may be entered.

Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either: (A) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and
examined under 37 CFR 1.129(b)(2); or (B) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2) even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26(a) states that "[T]he Commissioner may refund any fee paid by mistake or in excess of that required. A change of purpose after the payment of a
fee...will not entitle a party to a refund of such fee..." In this case, the fees paid under 37 CFR 1.129(b) were not paid by mistake nor paid in excess, therefore, applicant would not be entitled to a refund. In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101,
102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

14. The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. 103(b)" (1184 TMOG 86(March 26, 1996)):

> "However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all of the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

Therefore, in accordance with MPEP 821.04 and In re Ochiai, 71 F. 3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain

either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571-272-0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Coppins
May 14, 2004

CEILA CHANG
PRIMARY EXAMINER
GROUP 1200 1625